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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/002,864	11/15/2001	Helga Hoffmann	RDH 2350	4789

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SENNIGER POWERS LEAVITT AND ROEDEL
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16TH FLOOR
ST LOUIS, MO 63102

EXAMINER

GAKH, YELENA G

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 01/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/002,864	Applicant(s) HOFFMANN ET AL.	
	Examiner Yelena G. Gakh, Ph.D.	Art Unit 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/15/04.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 11-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☒ Claim(s) 1-9 and 11-42 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. The amendment filed on 11/15/04 is acknowledged. Claims 1-9 and 11-42 are pending in the application.

Response to Amendment

2. The objection of claim 8 is withdrawn in view of the amendment. The rejections are changed in light of the amendment.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. **Claims 1-9, 11-13, 20-26 and 27-33, 36-39 and 42** are rejected under 35 U.S.C. 103(a) as being unpatentable over Scholz (US 4,378,972) (Scholz I) in view of Scholz (US 5,139,955) (Scholz II).

Scholz I teaches one-component Karl Fischer volumetric titration agent comprising iodine and imidazole or its derivative from the group: “imidazole, 1-methylimidazole, 1-ethylimidazole, 1-propylimidazole, 1-butylimidazole, 2-methylimidazole, 2-ethylimidazole, 2-propylimidazole, 2-butylimidazole, 4-methylimidazole, 4-butylimidazole, 1,2-dimethylimidazole, 1,2,4-trimethylimidazole, 1-phenylimidazole, 2-phenylimidazole and benzimidazole, furthermore imidazoline, 2-methylimidazoline (lysidine), 2-phenylimidazole, and thiazole, 2-methylthiazole, 2-ethylthiazole, 4-methylthiazole, 4-ethylthiazole, 2-phenylthiazole, 4-phenylthiazole, benzothiazole, pyrimidine, 4-methylpyrimidine, 4-ethylpyrimidine, 1,3,5-triazine and 1,2,4-triazine” (col. 2, lines 23-37) or any imidazole represented by structure of claim 1. Suitable solvents are those of low molecular weight alcohols such as methanol (col. 2, line 40).

Scholz I does not specifically teach using a mixture of imidazole and its derivative.

Scholz II discloses a modified Karl Fischer reagent for coulometric analyses, in which iodine is replaced with iodide. “In Karl Fischer coulometry, the iodine necessary for the reaction is produced by anodic oxidation of the iodide” (col. 1, lines 23-25). In other aspects the reagent is the same as the one disclosed in Scholz I, except for Scholz II indicates that a mixture of imidazole and an imidazole derivative can be used for the reagent (col. 2, lines 8-10). Imidazole plays the same role in both types of Karl Fischer reagents – for volumetric and coulometric titration.

It would have been obvious for any person of ordinary skill in the art to slightly modify Karl Fischer reagent disclosed by Scholz I by using a mixture of imidazole and its derivative, as indicated in Scholz II, because it gives more flexibility in adjusting the composition of the reagent. It would have been obvious for anyone of ordinary skill in the art to optimize these ratios to obtain the best results for the reagent, see *In re Aller*, 105 USPQ 233 (CCPA 1955): “the use of optimum amount of a known reactant is within the ambit of one skilled in the art”.

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8. **Claims 14-19, 21 and 40** are rejected under 35 U.S.C. 103(a) as being unpatentable over Scholz I in view of Scholz II, as applied to claims 1-9, 11-13, 20-26 and 27-33, 36-39 and 42, and further in view of Fischer et al. (US 4,851,352).

Scholz I in view of Scholz II do not specifically disclose ethylene or diethylene glycol monoalkylethers as the alcohol solvents.

Fischer discloses Karl Fischer reagent containing alcohol solvents, comprising ethylene glycol monoalkyl ethers: "suitable ethylene glycol monoalkyl ethers are preferably those having an alkyl group containing 1-8 carbon atoms, particularly ethylene glycol monomethyl and monoethyl ether. Corresponding derivatives of the diethylene and triethylene glycol monoalkyl ethers are also suitable, for example, diethylene glycol monomethyl ether, etc." (col. 2, lines 17-24).

It would have been obvious for anyone of ordinary skill in the art to change alcohol solvent proposed for Karl Fischer reagent by Scholz I in view of Scholz II with the alcohol solvent of Fischer, because Fischer expands Schilz's list of suitable alcohol solvents by including various ethylene glycol monoalkyl ethers.

9. **Claims 34-35** are rejected under 35 U.S.C. 103(a) as being unpatentable over Scholz I in view of Scholz II, as applied to claims 1-9, 11-13, 20-26 and 27-33, 36-39 and 42, and further in view Sherman et al. (Accreditation and Quality Assurance, May 1999).

While Scholz I in view of Scholz II do not specifically indicate the optimal pH range for his Karl Fischer reagent, Sherman indicates "**pH of the KF [Karl Fischer] reagent (i.e., pH 5.5–8 with such bases as pyridine or imidazole**" [Google search with highlighted keywords, text excerpt from the article].

It would have been obvious for anyone of ordinary skill in the art to adjust pH of KF reagent disclosed by Scholz I in view of Scholz II to 5.5-8 with such bases as pyridine or imidazole, because this is the optimal pH range for this reagent, as indicated by Sherman.

10. **Claim 41** is rejected under 35 U.S.C. 103(a) as being unpatentable over Scholz I in view of Scholz II in view of Fischer as applied to claims 14-19, 21 and 40 above, and further in view of Sherman.

While Scholz I in view of Scholz II in view of Fischer do not specifically indicate the optimal pH range for his Karl Fischer reagent, Sherman indicates "**pH of the KF [Karl Fischer]**

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reagent (i.e., pH 5.5–8 with such bases as pyridine or imidazole” [Google search with highlighted keywords, text excerpt from the article].

It would have been obvious for anyone of ordinary skill in the art to adjust pH of KF reagent disclosed by Scholz I in view of Scholz II in view of Fischer to 5.5-8 with such bases as pyridine or imidazole, because this is the optimal pH range for this reagent, as indicated by Sherman.

Response to Arguments

11. While the Applicant's arguments filed on 11/15/04 are moot in view of the new rejections, the examiner would like to indicate that Scholz I discloses the same Karl Fischer reagent for volumetric titration as the one recited in the claims except for it comprises imidazole or any of its derivatives corresponding the structure of claim 1 or the list of claim 42, rather than a mixture of imidazole and one of these derivatives. Scholz II discloses Karl Fischer reagent for coulometric titration with substituting iodine with iodide and including a combination of imidazole with one of its derivatives. Since imidazole has the same function in both coulometric and volumetric reagents, it would have been obvious for any routineer in the art to use the same combination of imidazole with its derivative as disclosed by Scholz II for his Karl Fischer coulometric reagent in volumetric reagent disclosed by Scholz I, because it gives more flexibility in finding optimal ratio between the reagent components. The arguments regarding optimizing the ratio of imidazole and its derivative are not clear. If the mixture of imidazole and its derivative is used, it obviously has some proportion between its components. The proportion recited in claims and covering the range from ~1:10 to ~10:1 reveals non-specificity of the ratio for the reagent performance. The list of possible derivatives to be used along with imidazole indicates that no unexpected results can be predicted by using these combinations. Therefore, the claimed invention is obvious over the prior art.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yelena G. Gakh, Ph.D. whose telephone number is (571) 272-1257. The examiner can normally be reached on 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Yelena G. Gakh
1/12/05

